IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

BRAIDWOOD MANAGEMENT INC., et al.,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, et al.,

Defendants.

Case No. 4:20-cv-00283-O

BRIEF OF *AMICI CURIAE* AMERICAN MEDICAL ASSOCIATION, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, SOCIETY FOR MATERNAL-FETAL MEDICINE, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN MEDICAL WOMEN'S ASSOCIATION, AMERICAN ACADEMY OF FAMILY PHYSICIANS, NATIONAL MEDICAL ASSOCIATION, AND INFECTIOUS DISEASES SOCIETY OF AMERICA IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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IDENTITY AND INTERESTS OF *AMICI CURIAE*

Amici are medical associations and societies that represent practicing physicians who provide vital preventive health care services to millions of patients. *Amici* submit this brief to express their concern that an overly broad, nationwide remedy in this case could jeopardize the coverage of preventive health care services for millions of Americans and reverse positive trends in patient health that have been achieved by the early detection and treatment of diseases and other medical conditions.[1]

The **American Medical Association** is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. Founded in 1847, the AMA promotes the art and science of medicine and the betterment of public health, and these remain its core purposes. The AMA's members practice in every medical specialty and in every state. The AMA joins this brief on its own behalf and as a representative of the Litigation Center of the American Medical Association and the State Medical Societies. The Litigation Center is a coalition among the AMA and the medical societies of each state and the District of Columbia. Its purpose is to represent the viewpoint of organized medicine in the courts.

The **American College of Obstetricians and Gynecologists** is the nation's leading group of physicians providing health care for women. With more than 62,000 members, ACOG

[1] As noted in *amici*'s motion for leave, Defendants consent to the filing of this brief and Plaintiffs do not oppose its filing. Counsel for *amici* authored this brief in whole; no party's counsel authored, in whole or in part, this brief; and no person or entity other than *amici* and their counsel contributed monetarily to preparing or submitting this brief.

advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, and is committed to ensuring access to the full spectrum of evidence-based quality reproductive health care, including abortion care. ACOG's briefs and medical practice guidelines have been cited by numerous authorities, including the U.S. Supreme Court, as a leading provider of authoritative scientific data regarding childbirth and abortion.

The **Society for Maternal-Fetal Medicine,** founded in 1977, is the medical professional society for maternal-fetal medicine subspecialists, who are obstetricians with additional training in high-risk pregnancies. SMFM represents more than 5,500 members, including 442 in Texas, who care for high-risk pregnant people and provides education, promotes research, and engages in advocacy to advance optimal and equitable perinatal outcomes for all people who desire and experience pregnancy. SMFM and its members are dedicated to ensuring patients have access to preventive health care services to keep them healthy before, during, and after pregnancy.

The **American Academy of Pediatrics** was founded in 1930 and is a national, not-for-profit professional organization dedicated to furthering the interests of child and adolescent health. Since AAP's inception, its membership has grown from 60 physicians to over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 90 years, AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. Among other things, AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's children and adolescents to ensure the availability of effective preventive services.

The **American Medical Women's Association** is the oldest multi-specialty organization for women in medicine. Founded in 1915, AMWA's mission is to advance women in medicine, advocate for equity, and ensure excellence in health care. This is achieved by providing and developing programs in advocacy, leadership, education, and mentoring. AMWA and its members are dedicated to ensuring excellence in clinical care for all Americans.

Founded in 1947, the **American Academy of Family Physicians** is one of the largest national medical organizations, representing 127,600 family physicians and medical students nationwide. AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and by supporting its members in providing continuous comprehensive health care to all.

The **National Medical Association** is the collective voice of African American physicians and the leading force for parity and justice in medicine and the elimination of disparities in health. The NMA is the largest and oldest national organization representing African American physicians (over 50,000) and their patients in the United States. NMA is committed to improving the quality of health among minorities and disadvantaged people through its membership, professional development, community health education, advocacy, research, and partnerships with federal and private agencies. Throughout its history the National Medical Association has focused primarily on health issues related to African Americans and medically underserved populations; however, its principles, goals, initiatives, and philosophy encompass all ethnic groups.

The **Infectious Diseases Society of America** is a community of over 12,000 physicians, scientists, and public health experts who specialize in infectious diseases. Our purpose is to

improve the health of individuals, communities, and society by promoting excellence in patient care, education, research, public health, and prevention relating to infectious diseases.

INTRODUCTION

As professional organizations representing physicians across the country, *amici* know the value of preventive care services, ranging from colonoscopies and mammograms to weight loss and smoking cessation programs, in helping their patients to live long, healthy lives. Ensuring that patients can receive these services without financial barriers is of the utmost importance—and was one of the central features of the Affordable Care Act. Yet the "universal" relief sought by Plaintiffs, Suppl. Br. ISO Pls.' Mot. Summ. J. at 2, ECF No. 98, would gut the ACA's requirements and imperil access to these vital services nationwide. *Amici* file this brief to inform the Court of the repercussions that Plaintiffs' desired remedy could have on the availability of preventive care and to encourage the Court to exercise its equitable discretion to limit the terms and scope of any remedy that it orders accordingly.

The research is clear: no-cost preventive care saves lives, saves money, improves health outcomes, and enables healthier lifestyles. As medical professionals, *amici* know that preventive care can mean the difference between kicking a smoking habit or living with a heightened risk of dozens of illnesses; between taking a statin or suffering a life-changing heart attack; between providing essential prenatal care and screening or leaving children behind; and between catching a patient's cancer early or catching it after it's too late. Identifying and treating conditions before they worsen, or before they present at all, yields better outcomes for patients and saves money for the health system overall.

By expanding access to insurance coverage, and by requiring insurance plans to cover preventive health services without cost-sharing, such as copays and deductibles, the Affordable Care Act greatly expanded the availability of these services. In passing that statute, Congress

incorporated the service recommendations of the U.S. Preventive Services Task Force, an objective, rigorous body of experts—a decision that ensures that insurers only have to cover services that the available medical evidence demonstrates deliver high value to patients and the health system. The ACA's preventive-care requirements have functioned for more than ten years, enabling millions of Americans to obtain no-cost preventive care and improving utilization of these vital services nationwide.

Although the Court has concluded that certain aspects of this structure are unlawful, that fact does not in itself necessitate a remedy that renders the ACA's preventive-care requirements unenforceable, and thereby imperils access to preventive care, nationwide. Remedies are about equities, and those equities here include the ability of American patients to continue receiving no-cost preventive care as they have for over a decade. Rather than making it even harder for physicians to ensure their patients access these important services, we urge the Court to tailor the terms and scope of any remedy it orders to the limited extent necessary to redress the Plaintiff Braidwood Management's injuries.

ARGUMENT

I. Encouraging patients to obtain preventive care improves health outcomes and the functioning of the health system overall.

Preventive care is an umbrella term that refers to "[r]outine health care that includes screenings, check-ups, and patient counseling to prevent illnesses, disease, or other health problems."[2] As medical professionals, *amici* have an obligation to ensure that our patients, and the public as a whole, receive medically indicated preventive services. As Principle VII of the AMA Principles of Medical Ethics states, "A physician shall recognize a responsibility to

[2] *Preventive Services*, HealthCare.gov, https://www.healthcare.gov/glossary/preventive-services/ (last visited Nov. 28, 2022).

participate in activities contributing to the improvement of the community and the betterment of public health."[3] To that end, Opinion 8.11 of the AMA Code of Medical Ethics specifies that, "[w]hile a physician's role tends to focus on diagnosing and treating illness once it occurs, physicians also have a professional commitment to prevent disease and promote health and well-being for their patients and the community."[4]

An extensive body of evidence demonstrates how preventive care can help patients live long, healthy lives. Preventive services include both services aimed at the early detection and treatment of potentially fatal medical conditions and chronic diseases as well as services aimed at encouraging people to adopt healthy lifestyles. Preventive care can therefore "help people avoid acute illness, identify and treat chronic conditions, prevent cancer or lead to earlier detection, and improve health."[5] "When provided appropriately, these services can identify diseases at earlier stages when they are more treatable or may reduce a person's risk for developing a disease."[6] Similarly, "[i]mproved access to prenatal care is a public health gain as late entry into prenatal care or no prenatal care is known to contribute to poor birth outcomes, especially an increase in low birthweight and preterm babies."[7] Overall, a 2007 study by the National Commission on

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[3] *AMA Principles of Medical Ethics*, AMA Code Med. Ethics, https://code-medical-ethics.ama-assn.org/principles (last revised June 2001).

[4] *Opinion 8.11, Health Promotion & Preventive Care*, AMA Code Med. Ethics, https://code-medical-ethics.ama-assn.org/sites/default/files/2022-08/8.11.pdf (last visited Nov. 28, 2022).

[5] *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs. 1 (Jan. 11, 2022), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf [hereinafter *2022 ASPE Report*].

[6] *11th Annual Report to Congress on High-Priority Evidence Gaps for Clinical Preventive Services*, U.S. Preventive Servs. Task Force 5 (2021), https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/2021-uspstf-annual-report-to-congress.pdf.

[7] Susan Gennaro et al., *Improving Prenatal Care for Minority Women*, 41 Am. J. Maternity Child Nursing 147, 148 (2016),

Prevention Priorities estimated that "[i]ncreasing the use of just 5 preventive services," including several Task Force-recommended services, "would save more than 100,000 lives each year in the United States."[8]

Preventive care also reduces overall spending on health care. By "reduc[ing] the amount of undiagnosed or untreated conditions," preventive care "is expected to reduce costs through less invasive or complex treatment options."[9] Put simply, cancer is cheaper to treat at the outset than after it has metastasized. Although "[p]revention does not necessarily reduce medical costs as a rule," "[t]here are a number of preventive services that directly reduce costs," including "childhood immunizations, risky behavior counseling (*e.g.* smoking cessation, illicit drug abstinence), cardiovascular prophylaxis such as daily aspirin, and certain cancer screens."[10] Indeed, "[e]ighteen of the 25 preventive services evaluated by the [National Convention on Prevention Priorities] cost $50,000 or less per quality-adjusted life year (QALY) and 10 of these cost less than $15,000 per QALY, all well within the range of what is considered a favorable cost-effectiveness ratio."[11]

Despite the many benefits of preventive care, it can be difficult to encourage our patients to fully utilize these services. "Overall, Americans utilize recommended clinical preventive services at low rates, and utilization of preventive services such as cancer screening differs

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https://journals.lww.com/mcnjournal/Abstract/2016/05000/Improving_Prenatal_Care_for_Minority_Women.3.aspx.

[8] *Preventive Care: A National Profile on Use, Disparities, and Health Benefits*, P'ship for Prevention 6 (2007).

[9] Robert Brent Dixon & Attila J. Hertelendy, *Interrelation of Preventive Care Benefits & Shared Costs Under the Affordable Care Act*, 3 Int'l J. Health Pol'y & Mgmt. 145, 146 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4154552/pdf/IJHPM-3-145.pdf.

[10] *Id.*

[11] P'ship for Prevention, *supra* note 8, at 12.

across racial and ethnic populations."[12] "Commonly known reasons for not getting appropriate preventive services include lack of health insurance; lack of a usual source of care; and gaps in provider capacity, including wait times."[13] In particular, "[s]tudies have shown that out-of-pocket payments can be a barrier to the use of recommended preventive services, and reductions in cost sharing were found to be associated with increased use of preventive services."[14] Indeed, a 2012 meta-analysis of 47 separate studies found "strong[] support" for "the concept that cost sharing, as a financial barrier, decreases … the use of preventive services."[15] Prior to the enactment of the Affordable Care Act, the majority of Americans either lacked health insurance or were enrolled in insurance plans that did not cover preventive care without cost-sharing[16]—creating a substantial barrier to widespread use of preventive care.

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[12] *2022 ASPE Report*, *supra* note 5, at 7.

[13] Amanda Borsky et al., *Few Americans Receive All High-Priority, Appropriate Clinical Preventive Services*, 37 Health Affs. 925, 927 (2018), https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1248.

[14] Christine Leopold et al., *The Impact of the Affordable Care Act on Cancer Survivorship*, 23 Cancer J. 181, 184 (2017), https://journals.lww.com/journalppo/Fulltext/2017/05000/The_Impact_of_the_Affordable_Care_Act_on_Cancer.6.aspx; J. Frank Wharam et al., *Two-Year Trends in Cancer Screening Among Low Socioeconomic Status Women in an HMO-Based High-Deductible Health Plan*, 27 J. Gen. Internal Med. 1112, 1112 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3515008/pdf/11606_2012_Article_2057.pdf ("Previous research suggests that cost-sharing broadly reduces use of medical services, including cancer screening.").

[15] Reza Rezayatmand et al., *The Impact of Out-of-Pocket Payments on Prevention and Health-Related Lifestyle: A Systematic Literature Review*, 23 Eur. J. Pub. Health 74, 77 (2012), https://pubmed.ncbi.nlm.nih.gov/22544911/.

[16] Xuesong Han et al., *Has Recommended Preventive Service Use Increased After Elimination of Cost-Sharing as Part of the Affordable Care Act in the United States?*, 78 Preventive Med. 85, 87 (2015), https://www.sciencedirect.com/science/article/abs/pii/S0091743515002285?via%3Dihub.

II. The Affordable Care Act significantly expanded access to no-cost preventive care.

Congress passed the Affordable Care Act in 2010 "to improve national health-insurance markets and extend coverage to millions of people without adequate (or any) health insurance." *Me. Cmty. Health Options v. United States*, 140 S. Ct. 1308, 1315 (2020). Increasing access to preventive care is a core component of the scheme that Congress designed. As then-Secretary of Health and Human Services Kathleen Sebelius noted, "Many of the 10 major titles in the law, especially Title IV, Prevention of Chronic Diseases and Improving Public Health, advance a prevention theme through a wide array of new initiatives and funding."[17]

Specifically, Congress sought to eliminate cost-sharing requirements for accessing vital, evidence-backed preventive services.[18] In doing so, "the ACA transforms the U.S.'s public and private health care financing systems into vehicles for promoting public health."[19] As is relevant here, 42 U.S.C. § 300gg-13 mandates that

> A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—
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> (1) evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force….[20]

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[17] Howard K. Koh & Kathleen G. Sebelius, *Promoting Prevention through the Affordable Care Act*, 363 N.E. J. Med. 1296, 1296 (2010), https://www.nejm.org/doi/10.1056/NEJMp1008560?url_ver=Z39.88-2003.

[18] *See id.* ("A major strategy is to remove cost as a barrier to these services, potentially opening new avenues toward health.").

[19] John Aloysius Cogan Jr., *The Affordable Care Act's Preventive Services Mandate: Breaking Down the Barriers to Nationwide Access to Preventive Services*, 39 J.L. Med. & Ethics 355, 355 (2011), https://journals.sagepub.com/doi/10.1111/j.1748-720X.2011.00605.x.

[20] However, these requirements do not apply to so-called "grandfathered" plans, meaning plans that were in existence prior to 2010 and are therefore exempt from certain ACA provisions.

By incorporating the recommendations of the Task Force, Congress sought to ensure that insurers would be required to cover only effective, high-value services. "The [Task Force] is an internationally recognized, independent panel of nonfederal experts in primary care, prevention, and research methods that makes evidence-based recommendations to guide the delivery of clinical preventive services."[21] Some have even referred to the Task Force's methodology as the "gold standard" for clinical practice recommendations.[22] An "A" or a "B" recommendation indicates moderate to high certainty that the net benefits of a given service are moderate to substantial; other grades include "C," meaning that a service should be provided selectively, "D," meaning that a service is discouraged, and "I," meaning that there is insufficient evidence to assess the costs and benefits of a service.[23]

The Task Force has assigned a grade of A or B to 46 services, which have become core components of preventive medicine. These services include:

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[21] Janelle Guirguis-Blake et al., *Current Processes of the U.S. Preventive Services Task Force: Refining Evidence-Based Recommendation Development*, 147 Annals Internal Med. 117, 117 (2007), https://www.researchgate.net/publication/6260162_Current_Processes_of_the_US_Preventive_Services_Task_Force_Refining_Evidence-Based_Recommendation_Development.

[22] Doug Campos-Outcalt, *Practice Alert: US Preventive Services Task Force: The Gold Standard of Evidence-Based Prevention*, 54 J. Fam. Pract. 517, 517 (2005), https://cdn.mdedge.com/files/s3fs-public/Document/September-2017/5406JFP_PracticeAlert.pdf; Chyke A. Doubeni et al., *Viewpoint: Addressing Systemic Racism Through Clinical Preventive Service Recommendations from the US Preventive Services Task Force*, 325 J. Am. Med. Ass'n 627, 627 (2021), https://jamanetwork.com/journals/jama/article-abstract/2775793 (citing Inst. Med., *Clinical Practice Guidelines We Can Trust* (Robin Graham et al. eds., 2011)); Guirguis-Blake et al., *supra* note 21, at 117.

[23] *Grade Definitions*, U.S. Preventive Servs. Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/about-uspstf/methods-and-processes/grade-definitions (last updated June 2018).

- Screenings, genetic assessments, risk-reducing medications, and behavioral counseling for various cancers, including breast, colorectal, lung, skin, and various cancers of the female reproductive system.
- Preventive services for pregnant people and those who have recently given birth, including screening for aspirin use in those at high risk for preeclampsia, interventions to support breastfeeding, screenings for sexually transmitted diseases, folic acid supplements for neural tube defects, gestational diabetes screening, preventive medications for newborns, and blood testing.
- Precautionary screenings for certain population-wide diseases and conditions, including hepatitis, human immunodeficiency virus (HIV), and hypertension.
- Services for populations at high risk for certain conditions, including aneurysm screening in men aged 65 to 75 who have a history of smoking, cardiovascular disease screening among at-risk populations, tuberculosis screening, screening for osteoporosis in women aged 65 and older, screening for prediabetes and Type 2 Diabetes in adults aged 35 to 70 who are overweight or have obesity, and statin use in adults aged 40 to 75 years with cardiovascular risk factors.
- Preventive mental health screenings, including anxiety, depression, and suicide risk screening in children and adults.

- General, population-wide services aimed at encouraging healthy lifestyles, including obesity screening and weight loss programs, tobacco smoking cessation programs, and screening for unhealthy drug and alcohol use.[24]

In enacting the ACA, Congress sought to guarantee access to services like these regardless of financial constraints.

The ACA's preventive-care requirements have generally been successful in expanding access to preventive care, and for that reason, have proven to be one of the most popular parts of the statute.[25] "While some plans already covered the full costs of these services prior to the Affordable Care Act, millions of Americans were enrolled in health plans that did not."[26] In 2014, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services estimated that *76 million* individuals gained access to preventive care without cost-sharing as a result of the ACA, either by newly enrolling in private insurance or by having already enrolled in insurance plans that shifted to covering preventive care after the ACA's enactment.[27]

The number of Americans with insurance that covers preventive care with no out-of-pocket costs has only grown over the subsequent decade. "In 2020, the most recent year of data

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[24] *A & B Recommendations*, U.S. Preventive Servs. Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations (last visited Nov. 28, 2022).

[25] *See* Ashley Kirzinger et al., *5 Charts About Public Opinion on the Affordable Care Act*, Kaiser Fam. Found. (Apr. 14, 2022), https://www.kff.org/health-reform/poll-finding/5-charts-about-public-opinion-on-the-affordable-care-act-and-the-supreme-court/ (finding that 62% of Americans saw it as "very important" that preventive care requirements be kept in place).

[26] Amy Burke & Adelle Simmons, *Increased Coverage of Preventive Services with Zero Cost Sharing Under the Affordable Care Act*, Ass't Sec'y for Plan. & Evaluation, U.S. Dep't of Health & Human Servs. 2 (June 27, 2014), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//44251/ib_PreventiveServices.pdf.

[27] *Id.*

available," statistics indicate that "*151.6 million individuals* currently have private health coverage that covers preventive services with zero cost-sharing," including "approximately 58 million women, 57 million men, and 37 million children."[28] That figure includes nearly 13 million Texans.[29] The ACA's preventive-care requirements also apply to Medicaid expansion enrollees, adding another 20 million adults,[30] and to Medicare enrollees, if HHS has determined that a given service is appropriate for inclusion in the program, adding 61.5 million individuals more.[31] In other words, approximately *233 million individuals* are currently enrolled in health plans that must cover preventive services without cost-sharing because of the ACA.

This dramatic expansion of preventive coverage has generally increased the utilization of preventive services, although the available data is early and complicated by changes in Task Force recommendations over the relevant time period. A 2022 literature review of 35 separate studies conducted by the University of Michigan Center for Value-Based Insurance Design determined that "[t]he majority of findings in our literature conclude that cost-sharing elimination led to increases in utilization for select preventive services."[32] "Changes in utilization may be localized or augmented among specific populations, including low-income individuals, Medicare beneficiaries lacking supplemental insurance, and those with high levels of cost-sharing for a service pre-elimination," which "suggest that low-socioeconomic groups and those who experience the greatest financial barriers to care appear to benefit the most from cost-

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28 *2022 ASPE Report*, *supra* note 5, at 3 (emphasis added).

29 *Id.* at 5 tbl. 1.

30 *Id.* at 6.

31 *Id.* at 7.

32 Hope C. Norris et al., *Utilization Impact of Cost-Sharing Elimination for Preventive Care Services: A Rapid Review*, 79 Med. Care. Rsch. & Rev. 175, 192 (2022), https://www.deepdyve.com/lp/sage/utilization-impact-of-cost-sharing-elimination-for-preventive-care-bpUvb2r4Lr?key=sage.

sharing elimination."[33] To the extent preventive services remain under-utilized, it is because of additional barriers like lack of awareness of particular services or the benefits of preventive care.[34]

Similarly, a 2015 study found evidence of the ACA's efficacy for 64,000 adults with different insurance profiles.[35] The study observed that "the rate of uptake increased for some, but not all, recommended preventive services in which cost-sharing had been eliminated for many health plans during the first 2 years after implementation of the ACA provision."[36] In particular, it found that adults tended to utilize services like "[b]lood pressure check, cholesterol check, and flu vaccination," which "are mainly provided in physicians' offices especially during primary care office visit," but declined to fully utilize cancer screening services because, among other things, "those services are typically more complicated, more invasive, time-consuming, require more resources, and generally performed by specialists."[37] Overall, the authors concluded that their results suggested "some positive benefits of the provisions despite limited overall awareness and understanding of the ACA during the early days."[38]

Other studies have found significant increases in cancer screening rates. ASPE's 2022 report on preventive care utilization found that "[s]tudies examining changes in cancer screening

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[33] *Id.* at 193; *see also* Lindsay M. Sabik & Georges Adunlin, *The ACA and Cancer Screening and Diagnosis*, 23 Cancer J. 151, 161 (2017), https://journals.lww.com/journalppo/Fulltext/2017/05000/The_ACA_and_Cancer_Screening_and_Diagnosis.2.aspx ("Despite mixed findings, evidence to date suggests that impacts on screening were greatest among those with lower education and income, as well as groups that faced the highest cost-barriers to screening prior to the ACA. Thus, key populations targeted by the ACA's provisions appear to have benefited the most in terms of access to cancer screening.")

[34] Norris et al., *supra* note 32, at 193.

[35] Han et al., *supra* note 16, at 86.

[36] *Id.* at 87.

[37] *Id.*

[38] *Id.* at 89.

among privately insured individuals after the ACA eliminated cost-sharing show an overall increase in colorectal cancer screening tests," as well as "increase[d] cervical cancer screening rates among Latinas and Chinese-American women."[39] Another study found "a statistically significant increment in mammography uptake but not colonoscopy" among Medicare beneficiaries.[40] And a study of improvements in cancer screenings in community health centers found that "both increased insurance options (Medicaid expansion and subsidized exchange coverage) and preventive service coverage requirements (ensuring no out-of-pocket cost to patients for these screenings) helped patients obtain recommended services."[41]

Studies have also confirmed that the ACA's preventive care requirements increased the use of general wellness services. A 2014 study found that the expansion of insurance "accounted for the increase in young adults' receipt of a routine examination" in the preceding year, which "suggests that young adults will take initiative to seek a routine examination when financial barriers are removed."[42] It also found that "insurance accounted for the increase in receiving a blood pressure screening and accounted for part of the increases in receiving a cholesterol

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[39] *2022 ASPE Report*, *supra* note 5, at 7, 8.

[40] Gregory S. Cooper et al., *Changes in Receipt of Cancer Screening in Medicare Beneficiaries Following the Affordable Care Act*, 108 J. Nat'l Cancer Inst., no. 5, 2016, at 7, https://academic.oup.com/jnci/article/108/5/djv374/2412446; Heidi D. Nelson et al., *Mammography Screening in a Large Health System Following the U.S. Preventive Services Task Force Recommendations and the Affordable Care Act*, 10 PLOS One, June 2015, at 2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4487998/pdf/pone.0131903.pdf ("Mammography screening volumes in a large community health system decreased among women age <50 and ≥75 in association with new U.S. Preventive Services Task Force practice recommendations, while insurance coverage changes under the Affordable Care Act were associated with increased screening volumes among women age 50-74.")

[41] Nathalie Huguet et al., *Cervical and Colorectal Cancer Screening Prevalence Before and After Affordable Care Act Medicaid Expansion*, 124 Preventive Med. 91, 95 (2019), https://www.sciencedirect.com/science/article/pii/S0091743519301719.

[42] Josephine S. Lau et al., *Improvement in Preventive Care of Young Adults After the Affordable Care Act: The Affordable Care Act Is Helping*, 168 J. Am. Med. Ass'n 1101, 1105 (2014), https://jamanetwork.com/journals/jamapediatrics/fullarticle/1913624.

screening."[43] Similarly, "the percentage of Medicare beneficiaries utilizing annual wellness visits increased 14.9 percentage points between 2011 (the first year when such visits were covered) and 2016, rising from 8.1 percent to 23.0 percent."[44] Other studies have suggested that the ACA has made it more likely that pregnant persons will seek vital prenatal care.[45] These improvements mean that more Americans, including pregnant persons and children, are now able to take steps toward living healthier lives as a result of the Affordable Care Act.

Finally, the availability of no-cost preventive care has also improved utilization and health outcomes among populations that have historically been subjected to discrimination. Racial and ethnic disparities in health outcomes persist "even when access-related factors, such as patients' insurance status and income, are controlled."[46] In particular, "[r]acial and ethnic disparities in utilization of preventive care services are well-documented."[47] However, a recent study concluded that "[g]iven the large differences in the share of uninsured and the use of clinical preventive services among Black and Hispanic adults relative to White adults pre-ACA, the ACA does appear to have reduced the differences between minority adults and White

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43 *Id.*

44 *2022 ASPE Report*, *supra* note 5, at 8.

45 Yhenneko J. Taylor et al., *Insurance Differences in Preventive Care Use and Adverse Birth Outcomes Among Pregnant Women in a Medicaid Nonexpansion State: A Retrospective Cohort Study*, 29 J. Women's Health 29, 30 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6983742/pdf/jwh.2019.7658.pdf.

46 *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, Inst. of Med. 1 (Brian D. Smedley et al. eds., 2003), https://nap.nationalacademies.org/catalog/10260/unequal-treatment-confronting-racial-and-ethnic-disparities-in-health-care; *see also* Shirley A. Hill, *Inequality and African-American Health: How Racial Disparities Create Sickness* 11, 60 (2016).

47 Cagdas Agirdas & Jordan G. Holding, *Effects of the ACA on Preventive Care Disparities*, 16 Applied Health Econ. & Health Pol'y 859, 860 (2018), https://link.springer.com/article/10.1007/s40258-018-0423-5.

adults."[48] To take one example, "[t]he growth in the use of mammography (Hispanic women) and colonoscopy screening … increased at a higher percentage point rate among both Hispanic and Black adults compared with White adults with the implementation of the ACA."[49] Other studies have also found increases in cancer screening rates and improvements in blood pressure and glucose rates among members of historically marginalized communities.[50]

To be sure, the ACA's preventive care requirements are not a panacea; substantial additional work needs to be done to encourage patients to use the means provided to them to obtain these vital services.[51] But gutting the ACA's requirements would impose further barriers, making it even harder for *amici* to ensure that their patients receive the requisite care.

III. Nationwide relief would imperil access to preventive care for millions of Americans.

The Court should refrain from ordering any remedy that would allow insurers to reimpose cost-sharing requirements on the millions of Americans who currently have access to no-cost preventive care. Make no mistake—that is what Plaintiffs seek. Plaintiffs seek a "universal" remedy, which they characterize as a remedy that "prevents the [D]efendants from enforcing the disputed coverage mandates against *anyone*." Suppl. Br. ISO Pls.' Mot. Summ. J. at 2, ECF No. 98. Specifically, Plaintiffs have asked the Court to "set[] aside all Task Force recommendations with 'A' or 'B' ratings that were issued on or after March 23, 2010"; "set[]

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[48] Kenneth E. Thorpe, *Racial Trends in Clinical Preventive Services Use, Chronic Disease Prevalence, and Lack of Insurance Before and After the Affordable Care Act*, 28 Am. J. Managed Care, no. 4, April 2022, https://www.ajmc.com/view/racial-trends-in-clinical-preventive-services-use-chronic-disease-prevalence-and-lack-of-insurance-before-and-after-the-affordable-care-act.

[49] *Id.*

[50] *See, e.g.*, *2022 ASPE Report*, *supra* note 5, at 8, 10; Agirdas & Holding, *supra* note 47, at 869.

[51] *See, e.g.*, Borsky et al., *supra* note 13, at 928; Norris et al., *supra* note 32, at 193.

aside all other agency action taken to implement those Task Force recommendations"; and enjoin Defendants "from implementing" those recommendations or actions. *Id.* at 9.

The effect of these remedies would be to revert to the pre-ACA regulatory regime, where insurers could charge their enrollees—*amici*'s patients—for mammograms, colonoscopies, and other services at will. And yet Plaintiffs argue that "this Court *cannot deny* Braidwood a universal remedy." *Id.* at 10 (emphasis added). Plaintiffs are incorrect. Even assuming that the Administrative Procedure Act may *authorize* universal relief in this case (*but see* Defs.' Resp. Pls.' Suppl. Mot. Summ. J. & Cross Mot. for Summ. J. at 8-22, ECF No. 99), that is a far cry from *requiring* the Court to suspend its equitable discretion and vacate and/or enjoin agency rules nationwide, even when it would cause substantial public harm.[52]

"An injunction is a matter of equitable discretion" and courts must "pay particular regard for the public consequences" of imposing one. *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 24, 32 (2008) (citations omitted). Likewise, in deciding whether to vacate an agency's action, courts—including the Fifth Circuit—have long considered whether doing so would be "disruptive" to the public. *See Cent. & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (quoting *Radio-Television News Dirs. Ass'n v. FCC*, 184 F.3d 872, 888 (D.C. Cir. 1999)). In fashioning the terms and scope of an appropriate remedy, courts must therefore consider the effect that it will have on the public at large. *See Brown v. Plata*, 563 U.S. 493, 538 (2011) ("[B]readth and flexibility are inherent in equitable remedies.") (citations omitted). None of the

[52] *See also* Jonathan F. Mitchell, *The Writ-of-Erasure Fallacy*, 104 Va. L. Rev. 933, 1014 (2018) ("The authority to 'set aside' an agency's action also does not resolve whether courts should extend relief beyond the named litigants or issue 'nationwide injunctions' that extend beyond the court's territorial boundaries.") (citations omitted).

cases cited by Plaintiffs, Suppl. Br. ISO Pls.' Mot. Summ. J. at 10 n.7, ECF No. 98, are to the contrary.[53]

If the Court were to vacate and/or enjoin the Task Force's recommendations and any efforts to implement them on a nationwide basis, preventive care would be in grave jeopardy for tens of millions of Americans. As explained above, the most recent available data suggests that "*151.6 million individuals* currently have private health coverage that covers preventive services with zero cost-sharing," with another 81.5 million enrollees in Medicaid and Medicare programs that could also be implicated.[54] "Many health plans and self-insured employers would likely react" to a nationwide remedy "by imposing deductibles and copays for some or all the services recommended by the [T]ask [F]orce."[55]

Although it is difficult to know exactly how many plans would cease covering no-cost preventive services, and how quickly, statistics from prior to the enactment of the Affordable Care Act provide some clues. "According to the Kaiser Family Foundation's Employer Health Benefits Survey in 2012, 41 percent of all workers were covered by employer-sponsored group health plans that expanded their list of covered preventive services due to the Affordable Care Act."[56] But even assuming that only half that percentage today are covered by plans that would

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[53] Alternatively, if the Court is inclined to vacate the specified actions on a nationwide basis, it should stay that remedy during the pendency of any appeals and/or efforts by the agency to guarantee the continued availability of preventive services. *See, e.g.*, *AARP v. EEOC*, 292 F. Supp. 3d 238, 241 (D.D.C. 2017) (staying effective date of vacatur order for about one year "to avoid the potential for disruption"); *NAACP v. Trump*, 298 F. Supp. 3d 209, 244-45 (D.D.C. 2018) (staying vacatur order for 90 days to avoid disruption).

[54] *2022 ASPE Report*, *supra* note 5, at 3, 6-7 (emphasis added).

[55] Harris Meyer, *Court Ruling May Spur Competitive Health Plans to Bring Back Copays for Preventive Services*, Kaiser Health News (Sept. 15, 2022), https://khn.org/news/article/court-ruling-health-plans-copays-preventive-services/ [hereinafter Meyer, *Court Ruling*].

[56] Burke & Simmons, *supra* note 26, at 2.

revert to eliminating coverage or requiring cost-sharing means over *30 million Americans* could lose access to no-cost preventive services.

Patients who fall within that category could therefore face substantial out-of-pocket costs for obtaining preventive services. Imposing a copay or high deductible to access preventive services upon patients will deter some of them—and, in particular, those of limited means—from scheduling mammograms, colonoscopies, and screening tests for osteoporosis, hypertension, diabetes, lung cancer and other conditions that could shorten their lives if undetected and untreated.[57] Millions of patients could lose first-dollar coverage for cholesterol treatment, tobacco and alcohol cessation, and diet and obesity counseling. And pregnant persons and children will suffer from missing screenings and treatments during critical phases of pregnancy and early childhood. Deterring patients from receiving these vital services will result in worse health outcomes and impose higher costs on the health system to treat the maladies that emerge or worsen.

All Americans, however, will be affected by the confusion that emerges from gutting the ACA's decade-old preventive-care requirements. Doing so would yield a "confusing patchwork of health plan benefit designs offered in various industries and in different parts of the country," making it difficult for "[p]atients who have serious medical conditions or are at high risk for such conditions" to "find[] a plan that fully covers preventive and screening services."[58] Patients will, for the first time in ten years, have to scrutinize insurance plans to determine what preventive

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[57] *See* Meyer, *Court Ruling*, *supra* note 55 ("Tom York, 57, said he appreciates the law's mandate because until this year the deductible on his plan was $5,000, meaning that without that ACA provision, he and his wife would have had to pay full price for those services until the deductible was met. 'A colonoscopy could cost $4,000,' he said. 'I can't say I would have skipped it, but I would have had to think hard about it.'").

[58] *Id.*

services they cover, and at what out-of-pocket cost. And they will have to do so *both* when deciding which plan to select during enrollment, and then *again* when deciding whether to obtain a particular service. If the ACA's preventive-services requirements are later reinstated, those same patients may eventually have to revisit their insurance selections again. Many will instead decide to forgo basic preventive services entirely.[59]

Insurers will also alter their plans in ways that distort the functioning of the insurance system. Insurers would likely design their preventive services benefits to attract healthier customers, reducing their overall costs, or use cost-sharing requirements to lower premiums, forcing other insurers to follow suit to compete.[60] Even plans that hold out, and "keep a zero-cost policy for preventive services such as HIV prevention, diabetes screening, and lung cancer screening for smokers may gain a higher-risk population, forcing them to eventually add cost sharing to survive financially."[61] Put simply, "[y]ou end up with a race to the bottom"[62]—the precise opposite of what Congress sought to achieve in enacting the Affordable Care Act. Although some states might impose no-cost preventive care requirements by state law, only six

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[59] *See, e.g.*, Norris et al., *supra* note 32, at 193 (identifying "patients' unawareness of what services are exempt from cost-share" and "misperceptions of the importance of preventive care" as reasons patients decline to obtain preventive care); Stacey A. Fedewa et al., *Elimination of Cost-Sharing and Receipt of Screening for Colorectal and Breast Cancer*, 121 Cancer 3272, 3278 (2015), https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/cncr.29494.

[60] Meyer, *Court Ruling*, *supra* note 55; *see also* Harris Meyer, *What Will Payers Do If Courts Strike Down the ACA's No-Cost Requirement for Preventive Services?*, Managed Healthcare Exec. (Sept. 7, 2022), https://www.managedhealthcareexecutive.com/view/what-will-payers-do-if-courts-strike-down-the-aca-s-no-cost-requirement-for-preventive-services- [hereinafter Meyer, *What Will Payers Do*].

[61] Meyer, *What Will Payers Do*, *supra* note 60.

[62] *Id.*

states have done so thus far, and their authority to do so is limited to individual and small business health plans, not large employer plans.[63]

For these reasons, the Court should, at most, issue a remedy preserving the requirement that insurers cover the USPSTF's recommendations, but making those recommendations subject to review by the Secretary of HHS; a remedy limited to Plaintiff Braidwood Management; and/or a stay of any broader remedy the Court orders. *See* Defs.' Resp. Pls.' Suppl. Mot. Summ. J. & Cross Mot. for Summ. J. at 8-22, ECF No. 99. These more narrow remedies would help to preserve the effectiveness of the ACA's preventive care requirements, preventing any unnecessary disruption to vital screenings and treatments used by millions of Americans.

Such an approach is particularly appropriate for several additional reasons. First, an immediate nationwide remedy preventing the application of the ACA's no-cost preventive services requirements to *anyone* is plainly unnecessary to redress any injuries suffered by Braidwood Management, the only Plaintiff this Court has held to have standing thus far. Second, the Court's decision on the merits held only that the structure by which certain services are deemed subject to the ACA's no-cost preventive services requirements is unconstitutional, not that those requirements themselves are unconstitutional. Obstructing the Task Force's recommendations nationwide would therefore frustrate these otherwise unchallenged provisions by rendering them an effective nullity. And third, the Court's decision may well be subject to several rounds of appeal. There is no need to jeopardize Americans' access to vital preventive services while those appeals continue—particularly given that the U.S. Preventive Services Task Force's role in recommending specific services went unchallenged by industry for ten years.

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[63] Michael Ollove, *Lawsuit Could End Free Preventive Health Checkups*, Stateline, Pew Charitable Trusts (Aug. 9, 2022), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2022/08/09/lawsuit-could-end-free-preventive-health-checkups.

Ultimately, if this Court invalidates the Task Force's recommendations nationwide, physicians and healthcare professionals will be left in an untenable situation. *Amici* will struggle to encourage their patients to accept services that they know will save lives and to help their patients navigate a new and confusing insurance situation. *Amici* will see many of their patients, including some of their most vulnerable, turn down medically indicated services because of the very financial barriers that Congress sought to remove. The past ten years have shown the benefits of no-cost preventive coverage, and *amici* ask that the Court hesitate before ordering a remedy that could upset that substantial progress.

CONCLUSION

The Court should refrain from ordering any remedy that would imperil access to no-cost preventive care nationwide.

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Respectfully submitted,

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